K140247

APR 2 5 2014

angelus

510(k) Summary

Proprietary Name	MTA Fillapex
K Number	K140247
Date Prepared	April 25, 2014

Submitter	Angelus Industria de Productos Odontologicos Waldir Landgraf, 101 Londrina, Brazil 86031-3200 Telephone: +55 43 2101 3200
Official Contact	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL– (305) 377-0077

Common Name:	Resin, Root Canal Filling
Trade Name:	MTA Fillapex
Classification:	Class II
Product Code:	KIF
Classification Panel:	Dental
Regulation Numbers:	21 CFR 872.3820
Substantial Equivalence:	K113568 MTA Fillapex by Angelus K010940 Sealapex by Sybron

Description of Proposed Device

MTA Fillapex is a mineral trioxide aggregate (MTA) and resin toot canal sealer used during endodontic treatment to permanently fill the canal system following debridement and disinfection. It consists of two component pastes that are combined in a dual barrel syringe for ease of dispensing and consistent dosage. Being hydrophilic in nature, MTA-FILLAPEX is desirable as a root filling material because an isolated dry field is not necessary for use. Moisture does not negatively affect the sealing ability and is required for proper setting. It is used in combination with gutta-percha or silver points during root canal obturation.

Indications for Use

MTA-Fillapex is a root canal sealer intended for the permanent scaling of root canals and may be used in combination with root canal obturation materials.

angelus®
science and technology

Device Comparison Table

	Subject Device	Predicate Device	
	MTA Fillapex by Angelus K140247	K113568 MTA Fillapex by Angelus	K010940 Sealapex by Sybron
Indications for use	MTA-Fillapex is a root canal sealer intended for the permanent scaling of root canals and may be used in combination with root canal obturation materials.	MTA-Fillapex is a root canal sealer intended for the permanent scaling of root canals and may be used in combination with root canal obturation materials.	Sealapex 4 is a calcuium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic points.
Design	Two paste system (base/catalyst)	Two paste system (base/catalyst)	Two paste system (base/catalyst)
Flow	33.38 mm	27.66mm	25.15 (±1.73) mm (1)
Material components	Dicalcium and tricalcium silicate, tricalcium aluminate, calcium oxide, pentaerythritol rosinate, n-ethyl-o, p-toluenesulfonamide salicylate resin, bismuth oxide, fumed silica, titanium dioxide	Dicalcium and tricalcium silicate, tricalcium aluminate, calcium oxide, pentaerythritol rosinate, n-ethyl-o, p-toluenesulfonamide salicylate resin, bismuth oxide, fumed silica, titanium dioxide	Titanium Dioxide, Fumed Silica, Bismuth Trioxide, Isobutyl salicylate resin, N – ethyl toluene solfanamide resin, Calcium Oxide, Zinc Dioxide
Working time	23 minutes	35 minutes	Minimum 120 minutes
Setting time	Minimum 130 minutes	Minimum 130 minutes	45 minutes after placement
Solubility	2.47%	0.1%	>4% (2)
Shelf Life	2 years	2 years	2 years
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Standards	ISO 6876:2012	ISO 6876: 2001	ISO 6876: 2001

Substantial Equivalence

The subject device and the predicate devices have the same intended use and have the same technological characteristics, including the same range of physical and chemical properties. The subject and predicate devices are packaged in similar materials and utilize similar methods of application. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance Data

MTA Fillapex is a modification of K113568. They are designated for the equivalent dental applications and have comparable chemical and physical properties, and performance specifications. An additional predicate device (K010940) includes each specific chemical component that is equivalent to those found in MTA Fillapex, providing evidence that these materials are safe and effective for medical device use. Furthermore, MTA Fillapex and K113568 have equivalent packaging containers and delivery systems.

MTA Fillapex has undergone the following testing:

These tests have shown that MTA Fillapex and K113568 are substantially equivalent to the new MTA Fillapex. Both devices have comparable flowability, working times, setting times, dimensional change following setting, solubility, shelf life and biocompatibility properties.

Since MTA Fillapex's chemical composition is based on the principal chemical components in K113568, the biocompatibility test provides evidence that the product is non-mutenagenic, does not cause an allergenic potential after multiple uses and has a good tolerance. The shelf life, bench and biocompatibility testing, provide evidence that the chemical and physical properties are substantially equivalent.

Design Control Activities

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA) The design verification tests that were performed as a result of the risk analysis assessment are listed in the table below:

Modification	Test Performed	Acceptance criteria
Titanium dioxide was added to the base paste	1. Working time 2. Setting time 3. Flow 4. Radiopacity 5. Solubility Internal Tests 1. Flow/Viscosity 2. Radiopacity 3. Setting time 4. Free lime content	1. 23 minutes 2. 130 minutes 3. Minimum of 20 mm 4. Minimum of 3 mm 5. Maximum 3% 1. Base Paste 20-22 mm / Catalyst Paste 27-29 mm Mixed pastes after 30 min 21-23 mm 2. Greater than 3mm of the aluminium scale 3. 130 minutes 4. 3-5%

The test methods are the same as those submitted in the original submission.

angelus®
science and technology

Conclusion

MTA Fillapex has the equivalent indications for use, comparable chemical compositions, physical properties and performance specifications to K113568. The additional chemical component found in MTA Fillapex were found to be as safe and effective as the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Angelus Industria de Productos Odontologicos
C/O Tara Conrad
TechLink International Consulting
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

Re: K140247
Trade/Device Name: MTA Fillapex
Regulation Number: 21 CFR 872.3820
Regulation Name: Resin, Root Canal Filling
Regulatory Class: II
Product Code: KIF
Dated: March 14, 2014
Received: April 4, 2014

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: MTA Fillapex

510(k) Number: K140247

Indications for Use:

MTA-Fillapex is a root canal sealer intended for the permanent scaling of root canals and may be used in combination with root canal obturation materials.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Concurrence of CDRH, Office of Device Evaluation
(ODE) Page 1 of 1

Sheena A. Green -S
2014.04.25 12:35:13 -04'00'